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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/623,241

07/18/2003

Jurgen Horn

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09/27/2006

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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/623,241	<b>Applicant(s)</b> HORN, JURGEN	
	<b>Examiner</b> Dr. Kailash C. Srivastava	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 12-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 12-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

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## DETAILED ACTION

1. Applicant's response and amendment filed 27 June 2006 to Office Action mailed 28 March 2006 is acknowledged and entered.
2. In view of applicant's amendment, remarks and presentation of documents filed 27 June 2006 Examiner hereby withdraws following objections and rejections:
  - Objection to specification;
  - Rejections under 35 U.S.C. § 1112, 2<sup>nd</sup> paragraph to:
    - Claim 1 because of the recitation "including" and "Microbial content test agar"; and
    - Claim 8 for the phrase, "Microbial Content Test Agar".

## CLAIMS STATUS

3. Claims 10-11 have been cancelled.
4. Claims 12-14 have been added.
5. Claims 1-3, 5, 7 and 9 have been amended.
6. Claims 1-9 and 12-14 are pending and are examined on merits.

### *Claim Rejections Under 35 U.S.C. § 103(a)*

7. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.*

8. Claims 1-6, 8-9 and newly presented Claims 12-14 are rejected under 35 U.S.C. § 103 (a) as obvious over combined teachings from Kaiser (U.S. Patent 5,968,807) in view of Atlas et al.

(Handbook of Microbiological Media, CRC Press, Boca Raton, 1997, Pages 209-210 and 1272 for e.g.) and Horn (U.S. Patent 6,908,745).

Claims recite a culture medium comprising casein soy peptone gar supplemented with thioglycollate, sodium bisulfite, sodium thiosulphate and bromocresol purple to prepare a culture medium that is sterilized with gamma rays to detect microorganisms in presence of hydrogen peroxide. Claims further recite a method to detect microorganisms in hydrogen peroxide-bearing air or surface.

In response to rejections cited *supra* in Office Action mailed 28 March 2006, applicant argues that applicant's instantly claimed invention is unobvious over the combined or individual teachings from Examiner cited above references. Applicant further argues that because Examiner-cited references do not teach "a hydrogen peroxide neutralizing gamma-sterilisable medium" claimed invention is unobvious and there not even is a case to combine the references.

Applicant's above-cited arguments have been fully and carefully considered but are not persuasive because of the reasons of record and additional reasons discussed below.

First of all, applicant has introduced three new claims drawn o a method, not a composition without indicating support for those claims in either the specification, or previously presented claims. Secondly, applicant's arguments in regard to claimed invention not being obvious over Examiner-cited references are based on amended claims not he ones that were the basis for rejection in Office Action mailed 28 March 2006.

Although each of the Examiner-cited references by themselves do not teach every component as claimed in the claims under prosecution in the instant application, these references are not relied upon exclusively but in combination. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art at the time the invention was made. See *In re Keller* 642. F. 2d 413, 208 USPQ 871 (CCPA 1981). Furthermore, the 35 U.S.C. §103 statute does not

require that the prior art identically disclose or describe Applicant's invention but rather that no patent should be obtained if the subject matter as a whole would have been obvious to persons having ordinary skill in this art at the time the invention was made. In response to applicant's various citation that the claimed invention is discussed/elaborated or presented at great length in the specification (See applicant's remarks for e.g., at Page 10, Line 20-26 and Page 10, Line 31 to Page 11, Lines 6-9); the Applicant is reminded that the invention is the subject matter defined by the claims, and the limitations of the specification are not read in to the claims where no express statement of that limitations is included in the claims, (see *In re Priest*, 199 USPQ 11). Therefore, if the applicant is of the opinion that the Examiner is not comprehending applicants' invention as claimed in the instant application, the burden is on the applicant to clarify and claim the "surprising" aspects of the claimed invention and the aspects of said invention that the applicant regards as his invention.

In response to applicants' argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, those reasons are cited at pages 2-3, items 5-6 in Office Action mailed 28 March 2006 and for additional reasons discussed in item 8 *supra*. Furthermore, a rejection under 35 U.S.C. § 103 (a) based upon the combination of references is not deficient solely because the references are combined based upon a reason or technical consideration which is different from that which resulted in the claimed invention (*Ex parte Raychem Corp*, 17 U.S.P.Q. 2d 1417).

In response to applicant's arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

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**Prior Art of Record, Not Applied**

9. The prior art made of record and not relied upon is considered pertinent to Applicants' disclosure.

- CYRO TECH BRIEF, Sterilization Methods and Considerations. 2000 CYRO Industries, Rockway, N.J. 07866, Pages 1-6;
- Garcia et al. Strategies for Gamma Sterilization of Pharmaceuticals and Medical Packaging News, May 2004, Pages 1-4; and
- Difco Manual, 1998. Difco Laboratories, Sparks, MD 21152, U.S.A. 4 Pages.

***Claim Rejections Under 35 U.S.C. § 112, 2<sup>nd</sup> Paragraph***

10. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.*

**Rejections Maintained**

11. Claims 1-9 remain rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention.

- The phrase, "gamma-sterilizable" in Claims 1-9 renders those claims vague, unclear and indefinite, because said term indicates a futuristic event. The metes and bounds for said term are not defined in the claim language. Applicant should clearly define all the parameters for the term, "gamma-sterilizable".
- Phrase "hydrogen peroxide bearing situation" renders claim 1 vague, unclear and indefinite, because the metes and bounds for said phrase are not defined in the claim language. Applicant should clearly define all the parameters for the term, "hydrogen peroxide bearing situation".

All other claims depend directly or indirectly from the rejected claims (e.g., Claim 1) and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

In the response filed 27 June 2006 to above-cited rejections in Office Action mailed 28 March 2006, applicant argues that the “gamma sterilization is a well known art understood term”. Applicant further argues that the “phrase hydrogen peroxide bearing situation means an environment in which hydrogen peroxide is present”. Applicant subsequently presents a lengthy explanation for the phrase, “phrase hydrogen peroxide bearing situation”. Applicant also presents citations from the specification to make the point about what are the dosage for gamma radiated mediated sterilization and the difficulties of identifying specific colonies on culture media sterilized with gamma irradiation See Remarks Page7, Lines 24-28 for example).

Applicant’s arguments filed 27 June 2006 to above-cited rejections in Office Action mailed 28 March 2006 regarding the rejections to Claims 1-9 have been fully and carefully considered but are not persuasive for the reasons of record at page 4 of the Office Action mailed 28 March 2006 and for the reasons discussed *infra*.

Applicant is correct and the Examiner is well aware that “gamma irradiation is a well known art understood term”. However, the rejection is to phrase “gamma-sterilizable” because the metes and bounds for said phrase are not defined and said phrase indicates a futuristic event. Similarly, applicant has very well explained the phrase, “hydrogen peroxide bearing situation” in the argument, however, the claim language does not recite that language. Applicant should appropriately correct the [phrases, “gamma-sterilizable” and “hydrogen peroxide bearing situation”. Applicant is also reminded that although claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., *In re Van Guens*, 988 F.2d 1181, 26 PSPG2d 1057 (DED. Cir. 1991). Accordingly, without the recitation of all the critical limitations as set forth above, the claims do not adequately define the instant invention.

#### ***New Rejections Under 35 U.S.C. § 112, 2<sup>nd</sup> Paragraph***

12. In view of applicants’ amendments filed 28 March and 01 June 2006, following are new rejections to claims 26-28 under 35 U.S.C. §112, second paragraph.

- The phrase, “gamma-sterilizable” in Claims 12-14 renders those claims vague, unclear and indefinite, because said term indicates a futuristic event. The metes and

bounds for said term are not defined in the claim language. Applicant should clearly define all the parameters for the term, "gamma-sterilizable".

- Claims 13-14 recite the limitation "A method as set forth in Claim 1" at Line One. There is insufficient antecedent basis for this limitation in Claims 13-14 because Claim on which Claims 13-14 are dependent is drawn to a composition, not to a method.

### **Conclusion**

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. For the aforementioned reasons, no claims are allowed.

However, Claim 7 may be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. §112, 2nd paragraphs, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.


15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday



8:00 A.M. to 4:30 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

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September 18, 2006



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